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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,383	08/21/2003	Vincent G. Copa	AMS0008/US	9726
33072	7590	02/25/2009		
KAGAN BINDER, PLLC SUITE 200, MAPLE ISLAND BUILDING 221 MAIN STREET NORTH STILLWATER, MN 55082				
EXAMINER				
YABUT, DIANE D				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
02/25/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/646,383

**Applicant(s)**

COPA ET AL.

**Examiner**

DIANE YABUT

**Art Unit**

3734

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-14 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-14 and 26-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/23/2009 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-9, 11-14, and 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Salama** (U.S. Patent No. **5,306,226**) in view of **Kirsch et al.** (U.S. Patent No. **6,461,367**).

Salama discloses a hollow elongate, flexible catheter body having a proximal end and a distal end, an inflatable balloon **26** at the distal end in the bladder, a drainage aperture **18** at the distal end and a drainage means **15** connected to the drainage

aperture for draining urine from a bladder, and tissue approximating structure or means **36** on the catheter body capable of contacting bladder and being on a proximal side of the inflatable balloon, tissue of a perineal wall, urethral tissue, and combinations of these for holding severed tissue in contact for healing, wherein the inflatable balloon is on a proximal side of the drainage aperture (Figure 2, col. 2, lines 18-56).

Salama discloses the claimed device, including a tissue approximating structure or means located on a proximal side of the drainage aperture, *except for* the tissue approximating structure comprising a distal tissue approximating structure and proximal tissue approximating structure both comprising movable elongate tines positioned to extend and retract through apertures in the catheter body wall at the distal end of the catheter body, wherein the distal and proximal tissue approximating structures are extended and retracted using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end.

Kirsch et al. teach a method and device for urethral-vesicle anastomosis following a prostatectomy comprising movable elongate structures or multiple opposing tines that hold severed tissue together, including a distal tissue approximating structure **108** and a proximal tissue approximating structure **110** which can be extended and retracted from apertures **106** in a catheter body at the distal end using actuating mechanisms **112**, **114** that extend through a lumen along a portion of the length of the device to the proximal end (Figures 14 and 17-18). It would have been obvious to one of ordinary skill in the art at the time of invention to replace the tissue approximating structure or means of Salama with one comprising multiple opposing tines at the distal

end of a catheter body, as taught by Kirsch et al. in order to facilitate the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines, making the process more efficient and simple to use (col. 1, lines 38-40, Kirsch et al.). It also would have been obvious to modify Salama with movable tissue approximating tines in order to facilitate tissue approximation by allowing the catheter, or the device within the catheter, to move without being engaged to the tissue until it is at a desired location at which point the tines can be extended.

#### ***Response to Arguments***

4. Applicant's arguments with respect to claims 1-9, 11-14, and 26-34 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734